

Dendreon – sipuleucel-T (Provenge) - BLA STN 125197

For the treatment of men with asymptomatic metastatic androgen independent prostate cancer

BLA Filing Meeting, December 19, 2006

1. Advisory committee updates – 5 min (Liu, Simek)

- Sponsor notified 12/5/05
- Updates
 - FR Notice
 - Draft Agenda
 - Committee composition

2. Administrative – 10 min (Tull)

- eRoom explanation
- Review of BLA timelines (See Attachment)
- Outreach activities
 - OODP briefing Jan. 29
 - Briefing Dr. Goodman

3. Review updates – 30 min (Review team)

- Deficiencies, communications, status, etc.
 - CMC
 - Clinical/Statistical: Primary endpoint: Time to objective disease progression (Clinical draft review in progress)
 - Pharm/Tox
 - OBE
 - OCBQ
 - BIMO

4. Discussion regarding acceptability for filing – 30 min (All)

- Checklist
- Deficiencies/letter comments
- Internal sign-off deadlines?
- Filing letter due January 20, 2007

5. Action Items

Concerning the advisory committee meeting

- Send bullet items to Steph about why this product is coming to OCTGTAC and not ODAC [Ke and Keith]
- Schedule a meeting to discuss agenda details (who presents, how much time, goals of presentations, will sponsor or CBER present first etc) [Lori]

Concerning the BLA calendar

- Add deadline for providing briefing document to Celia and OODP (February 20)
- Add inspection dates to calendar (week of February 12th)

Concerning filing

- Lori will provide review team with template for filing recommendation
- Review team will return concurred memo containing filing recommendation

OCTGT:IOD:L.Tull:12/19/06

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